

Swedish Enterprise´s position on the Chemical Strategy

The Importance of a holistic Chemicals strategy

In October 2020, the European Commission presented a Chemicals Strategy with a large number of proposals and measures. In this document, Confederation of Swedish Enterprise comments on the Chemicals Strategy in general and on specific proposals.

Swedish Enterprise is Sweden´s largest business federation, representing 60 000 member companies in all sectors with almost 2 million employees. We bring together 49 industry and employer organisations, and this position has been produced in close cooperation with our members.

The role of chemistry in society and value chains

Our ability to use chemistry to produce goods and services that help us in our daily lives is fundamental to human health and the prosperity of society. It is thanks to chemistry and research and innovation that we are able to produce goods and services we rely on in our daily lives. It allows us to make medicines and vaccines, semiconductors for our digital society, wind turbines and solar panels that generate fossil-free energy, soaps and disinfectants that prevent disease and process chemicals enables manufacturing of fossil-free steel and converting biomass into useful products. In short, chemistry is an essential prerequisite for delivering a sustainable society.

The Chemicals Strategy and the revision of the chemical legislation must adopt a holistic and value chain perspective. If not, the society´s capacity to produce goods and services for our prosperity might be at risk. For the same reason, the implementation of the Chemical Strategy is not just a matter of environmental policy; it is also a decisive issue for economic policy.

The objectives and implementation of the Chemicals strategy

The Business Community supports the goals set out in the Chemicals Strategy of delivering a high level of protection for health and the environment while promoting safe and sustainable chemistry. Yet, in order for this to be achieved while maintaining business competitiveness, promoting innovation and ensuring continuing societal prosperity, implementation must be conducted in close cooperation with business. It needs to take the broader needs, of business and society, for chemicals into account. Therefore, the likely impact of the proposed Chemicals Strategy must be carefully analysed, particularly from the perspective of value chains' need for and access to chemicals. It is vital that the implementation of the Strategy is balanced, that it recognises society´s need for access to chemicals and reflects their role in sustainable development.

Generic approach to risk management (GRA)

The European Commission proposes to expand the concept of Generic Approach to Risk Management (GRA) for consumers and professional users of chemical products. In practice, this implies a ban on products with certain hazard classifications if their use is not deemed essential for society. This would mean that substances and products that can be used safely but are not defined as necessary for society, would need to be phased out. This is despite the fact that these could be of considerable societal benefit.

The consequences of introducing this new fast track for restricting products in combination with the introduction of new hazard classes, (see comments on CLP below), are difficult to predict. According to a report by Ricardo Energy and Environment¹, up to 12,000 substances may be subject to different regulatory conditions if the implementation of new hazard classes under CLP and its regulation in downstream legislation is carried out without consideration of the needs of value chains. In the continuing implementation of GRA, it is important to consider the following:

- Implementation needs to proceed in a stepwise manner, so as not to risk undermining competitiveness or inhibiting the climate transition;
- The GRA needs to prioritise consumer use, with a high probability of exposure to the most dangerous chemicals. Professional users must be primarily protected through relevant occupational legislation and/or through targeted training;
- Implementation needs to take account of the individual requirements of, and opportunities for, substitution in value chains. In addition, the implementation should not be subject to an arbitrarily set end date in the legislation.

Permits, restrictions, and Essential use

There is a pressing need to streamline and improve authorisation and restriction processes to make them predictable, accurate and to allow them to optimise the use of business and government resources. To this end, the concept of “essential use” or “necessary for society” is discussed. This is a broad concept, and it is unclear how the assessment of which products or areas of use are “necessary for society” and how they should be defined. Therefore this concept must be used with considerable caution and only be used to inform decisions on whether an area of use should be granted an exception within a restriction or granted authorisation for production or use in a given process.

Implementation of the concept needs to be based on scientific evidence. Subjective judgments must be avoided as it risks leading to prolonging and complicating permit and restriction processes, instead of making them faster, as authorities will have to spend longer on lengthy discussions on exceptions to uses defined in advance as “necessary for society”. If the concept of “essential use” is to be implemented in legislation, the implementation must be based on the following:

- A politically appointed group or committee should be mandated to decide on what is necessary to society; this body should also take responsibility for the consequences of case-by-case decisions;

¹ [Economic-Analysis-of-the-Impacts-of-the-Chemicals-Strategy-for-Sustainability-Phase-1.pdf \(cefic.org\)](#)

- The concept must be used to support decision making in permit/restriction processes, not as a specific justification for regulation;
- If a use can be demonstrated to be safe, it must be permitted irrespective of whether or not the area of use is deemed socially necessary.

New hazard classifications under CLP

The European Commission is proposing that new hazard classes be added to the CLP legislation. There are connections between CLP and sector-specific legislation, for example for biocides, pesticides, detergents, toys and medical technologies. New hazard classes under CLP legislation would not only affect the chemical industry, but also have a major impact on downstream chemical users. This would generate a significant amount of work for all those who use chemicals, or are dependent on chemicals for their production processes. Therefore this must be balanced against the environmental or health benefits that any new hazard classes are deemed to provide.

The CLP Regulation is based on the Globally Harmonised System of Classification and Labelling of Chemicals (UN GHS), which is a key element for the safe handling of chemicals worldwide. Any deviations from these worldwide standards runs the risk of disrupting global value chains and undermining trust in existing well-functioning global collaborations and systems. As the majority of companies currently operate globally, importing and exporting all over the world, this also risks creating trade barriers.

To minimise the negative consequences of revising the CLP regulation, the new legislation must:

- Be harmonised with global standards;
- Be assessed for its impact on downstream users' need for access to chemicals. A thorough review needs to be undertaken to determine how strategic value chains are likely to be affected by proposed changes to CLP legislation.

Mixture effects and the introduction of the Mixture Assessment Factor (MAF)

As part of the chemicals strategy, the European Commission is proposing the introduction of requirements for a safety factor (MAF) to address combination effects, such as unforeseen exposure to different chemicals in the environment simultaneously. A MAF is being proposed for all risk assessments to ensure that unforeseen mixtures and combinations are safe for human health and the environment. There has been a considerable number of studies and research carried out recently. According to one of the reports dealing, with the review of chemicals in surface water, the unilateral application of a MAF does not lead to increased protection of health and the environment. The study shows that 90 % of the chemical mixtures studied are not of concern. Some 5 % of the mixtures could pose a risk but these are already managed - or can be managed - through improving application of the existing legislation. In fact, only 5 % of the mixtures studied may pose a risk not currently controlled by existing chemical or environmental legislation.

Given these data, adding a safety factor to all substances and all areas of use would create an unreasonable workload for society and industry with unclear added value for the protection for health and the environment. Important substances risk being removed from the market before any appropriate replacements or substitutes have been developed. This would leave downstream users without substances they need for production. Alternatively, they would have to expend considerable resources to draw up their own chemical safety reports for specific applications, a very challenging task, particularly for small and medium-sized companies. Introducing a MAF in the legislation must therefore be applied accurately to those substances and areas of use that pose a mixing risk. A MAF should be applied to substances according to decisions based on those substances that:

- are produced in large volumes *and*
- have widespread applications and are therefore likely to create extensive exposure *and*
- are classified as having long-term environmental effects.

Enforcement, compliance and a global perspective

The EU's REACH legislation is the world's most comprehensive chemical legislation and provides a very high degree of protection for health and the environment. It is positive that the EU has high ambitions in the chemicals area, something that companies in Sweden share. Yet Sweden and the EU are part of a global context and businesses in Sweden are highly dependent on imports and exports. Therefore, while it is important that the EU's chemical legislation is ambitious, at the same time it must be adapted to global realities and ensure the EU's ongoing competitiveness. This means, for example, avoiding situations where deviations from the GHS create trade barriers, by ensuring that the criteria for classification align with global standards. Further, the same rules must apply to non-European companies exporting goods to the EU as apply to those companies choosing to locate their production in Europe. A clear strategy for improving how regulatory compliance is enforced is needed, particularly for imported products and e-commerce platforms.

If Europe is to defend its global competitiveness while simultaneously protecting health and the environment as well as it can, it must be ensured that:

- Sweden takes the lead in developing and driving enforcement in the EU
- The same rules apply to producers, both inside and outside the EU, through effective and tough enforcement of imports.
- Products imported via e-commerce platforms meet the EU's chemical requirements.

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